REMARKS

Claims 30-75 are pending in the present application. Claims 30-75 were rejected. By virtue of this response, Claims 30, 38, 39, 51, 57, and 63 have been amended. Claims 76-121 were previously presented in the Amendment to Copy Claims filed by Applicants on August 1, 2007. New Claims 122-134 have been added. Accordingly, Claims 30-134 are currently under consideration. Amendment of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicants expressly reserve the right to pursue prosecution of any presently excluded claim embodiment in future continuation, continuation-in-part, and/or divisional applications.

Amendments

Claims 30, 38, 39, 51, 57, and 63 have been amended, and new Claims 122-134 have been added. Support for the amendment of Claims 30, 38, and 39 may be found, for example, at page 7, paragraph [0030] and page 9, paragraph [0034]. Support for the amendment of Claims 51, 57, and 63 may be found, for example, at page 7, paragraph [0028]. Support for new Claims 122 and 123 may be found, for example, at page 13, paragraphs [0049] and [0050] of the specification. Support for new Claims 124, 127, and 129 may be found, for example, at page 7, paragraph [0030] and page 9, paragraph [0034] of the specification. Support for new Claims 125, 128, and 130 may be found, for example, at page 7, paragraph [0030] of the specification. Support for new Claims 126 and 131 may be found, for example, at page 7, paragraph [0028] and pages 8-9, paragraph [0037] of the specification. Support for new Claims 132, 133, and 134 may be found, for example, at pages 8-9, paragraph [0033] of the specification.

Office Communication dated October 19, 2007

In an Office communication dated October 19, 2007, the Examiner alleged that the Amendment to Copy Claims filed by Applicants on August 1, 2007 appeared to be a bona fide attempt at a response to the Non-final Office Action dated July 6, 2007, but was non-responsive. Applicants note the Amendment to Copy Claims dated August 1, 2007 states at page 1 that "[t]his amendment is not a response to the non-final Office Action issued on July 6, 2007; rather, that Office Action will be addressed in a separate filing." Applicants respectfully request that the

Office communication dated October 19, 2007 be withdrawn by the Office on the record. Nevertheless, Applicants respectfully submit that the present amendment is fully responsive to the Office Action.

Claim Rejection – 35 U.S.C. § 102

Claims 30-75 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Mollison (U.S. Patent 6,015,815). Applicants respectfully traverse this rejection.

The Examiner alleges that "Mollison teaches the use of rapamycin analogs in combination with an alcohol such as ethanol and propylene glycol for the treatment of wet form macular degeneration" and that "ophthalmic mode of administration is taught." Office Action at page 2. Applicants respectfully disagree.

Applicants first note that Applicant's claims are directed to a combination of a therapeutic agent such as rapamycin and polyethylene glycol (PEG), not the combination of a therapeutic agent and propylene glycol which the Examiner cites the Mollison reference as teaching at page 2 of the Office Action.

The claims as amended are directed to compositions containing polyethylene glycol that are suitable for ocular injection and use of compositions containing polyethylene glycol for treatment and prevention of various ocular diseases. Mollison does not disclose compositions comprising polyethylene glycol suitable for ophthalmic administration by injection, and Mollison does not disclose methods of treating or preventing an ocular disease or condition comprising an effective amount of rapamycin and polyethylene glycol.

Regarding vehicles that may be used in the compositions described by Mollison, Mollison does not disclose compositions comprising polyethylene glycol for ocular use. Polyethylene glycol is described as a suitable vehicle for intravenous administration, parenteral administration, solid oral dosage forms, and liquid oral dosage forms, but not for ocular use. Mollison states at column 11, line 64 – column 12, line 7 that for ***parenteral injection*** "suitable aqueous and nonaqueous carriers, diluents, solvents or vehicles include ... ethanol, polyols (such as glycerol, propylene glycol, polyethylene glycol, and the like) ...." Mollison further states at column 12,

line 51 – column 13, line 5 and column 13, lines 24-36 that solid dosage forms and liquid dosage forms for ***oral administration*** includes pharmaceutically acceptable excipient or carrier such as solid polyethylene glycols or solubilizing agents and emulsifiers such as ethyl alcohol and propylene glycols, respectively. In contrast to parenteral and oral administration, Mollison does not disclose the combination of a therapeutic agent such as rapamycin or a rapamycin derivative and polyethylene glycol for use in composition suitable for ophthalmic administration.

Regarding ocular administration, Mollison describes only topical administration and does not describe either intravitreal or subconjunctival administration. In regards to topical administration to the eye, Mollison states that suitable inert carriers include sugars such as lactose, and the ophthalmic vehicle may be an ointment, vegetable oil, or an encapsulating material. *See* column 13, line 46 – column 14, line 17. Mollison does not disclose a composition comprising the combination of a therapeutic agent such as rapamycin or a rapamycin derivative and polyethylene glycol suitable for ophthalmic administration by injection.

Mollison does not disclose a composition comprising rapamycin and polyethylene glycol which is suitable for ophthalmic administration by injection as recited in independent Claim 30. Mollision also does not disclose a composition of rapamycin dissolved in polyethylene glycol and ethanol, wherein the composition contains an amount of rapamycin effective to treat wet form of age-related macular degeneration, which is suitable for ophthalmic administration by injection, as recited in independent Claim 38. Further, Mollison does not disclose a polyethylene glycol based ocular composition comprising polyethylene glycol and a therapeutic agent, which is suitable for ophthalmic administration by injection, as recited in independent Claim 39. Claims 31-37, 40-50, and 68-75 depend from independent Claims 30 and/or 39, directly or indirectly.

Applicants note that Mollison states that the compounds of the invention in Mollison (which do not include rapamycin) are useful in the treatment and prophylaxis of certain ocular diseases including senile macular degeneration. See column 8, line 52 – column 10, line 29. Rapamycin, on the other hand, is recited in Mollison in a list as one of a number of immunosuppressant agents that may be co-administered with the compounds of the Mollison invention. Mollison nowhere states that rapamycin is useful in the treatment and prophylaxis of ocular diseases such as senile macular degeneration or other ocular diseases or conditions.

Further Mollison does not teach an effective amount of rapamycin to treat or prevent the wet form of age-related macular degeneration.

Mollison does not disclose a composition of rapamycin dissolved in polyethylene glycol and ethanol, wherein the composition contains an amount of rapamycin effective to treat the wet form of age-related macular degeneration as recited in independent Claim 38. Also, Mollison does not describe a method for treating or a method of preventing wet form of age-related macular degeneration comprising administering a composition comprising an effective amount of rapamycin to treat or prevent wet form of age-related macular degeneration dissolved in polyethylene glycol and ethanol as recited in independent Claims 51 or 57. Further, Mollison does not describe a method for inhibiting the transition in a human from the dry form of age-related macular degeneration to wet form of age-related macular degeneration comprising a composition comprising an effective amount of rapamycin to inhibit the transition in a human from the dry form of age-related macular degeneration to wet form of age-related macular degeneration dissolved in polyethylene glycol and ethanol as recited in independent Claim 63. Claims 52-56, 58-62, and 64-67 depend from independent Claims 51, 57 and/or 63, directly or indirectly.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 30-75 under 35 U.S.C. § 102(b) as allegedly being anticipated by Mollison (U.S. Patent 6,015,815).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 11-1410. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1-4-08

By: Ryan Melnick

Ryan E. Melnick
Registration No. 58,621
Attorney of Record
Customer No. 20,995
(619) 235-8550

4705358:sad
010308